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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,588	09/18/2000	Jaime Vargas	032405-003	4754

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CARDICA, INC.
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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

34

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,588

Applicant(s)

VARGAS ET AL.

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-60, 64-72 and 76-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 41-49 and 53-60 is/are rejected.
- 7) ☒ Claim(s) 39, 40 and 50-52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 30.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure does not support a "cam groove [is] defined *in* the member." For purposes of examination, examiner considers the member within the cam groove.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60, 64-72, and 76-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaster et al. (US 5,403,333). Kaster discloses an anastomosis system comprising a unitary anastomosis device (Fig. 10), a first member (Fig. 5), a second

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member (Fig. 3), a handle 32 and 33, a unitary anastomosis device (Fig 10) and a flange 44.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(c) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 38, 41-43, 46 and 53-59 are rejected under 35 U.S.C. 103(c) as being unpatentable over Bolduc et al. (US 6,193,734).

The embodiments of Figs. 10-12 illustrate an anastomosis system comprising a holder tube 18B, an expander 16B, a trocar 34B, a plurality of slits/hooks 40B for receiving pull-tabs 38B, and a "handle" 16 and 18. The "handle" may be rotated, though not necessarily rotated relative to any other part of the device.

Although Bolduc discloses an anastomosis device in the embodiment, the embodiment fails to disclose a unitary anastomosis. Nevertheless, Bolduc teaches in Figs. 27-28 two embodiments of a unitary anastomosis device, which is used to provide stability to the anastomosis device and graft vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the anastomosis device unitary, as taught in Figs. 24 and 25, to stabilize the anastomosis device and graft vessel.

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Claims 44 -49 are rejected under 35 U.S.C. 103(c) as being unpatentable over Bolduc in view of Kaster et al. Bolduc fails to disclose a plurality of flexible fingers. Nevertheless, Kaster teaches the use of flexible fingers to secure the anastomosis device to the holder tube. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Bolduc device to include fingers to more effectively secure the anastomosis device to the holder tube.

Bolduc also fails to disclose the details of a handle. Nevertheless, Kaster discloses a rotating handle 32 and 33 used to advance an expander. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include handle on the Bolduc device, as taught by Kaster, in order to advance the expander.

Kaster's handle 33 moves relative to the holder member. It can be considered that the handle member 33 of Kaster's device remains in position while the handle portion 32 is moved. This results in the handle moving the holder tube. The handle comprises a grip 32 and 33, and a member 37 located within a "cam groove."

Allowable Subject Matter

Claims 39, 40 and 50-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Examiner agrees that the entire Bolduc anastomosis device does not expand. However, the outer diameter of the lower portion of the legs 30 do expand radially. Examiner further agrees that the embodiment of Figs. 16-30B do not disclose an expander since the anastomosis device is released by stored energy. The rejection of claims 46-48 on the grounds of inherency has been withdrawn.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD
February 20, 2004


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700